

Appl. No. : 10/036,041
Filed : December 26, 2001

REMARKS

After entry of the foregoing amendments, Claims 26 and 35 has been amended. The amended claims are supported by the specification and the claims as originally filed. No new matter has been added. Claims 27-29 and 32-34 have been cancelled without prejudice toward future prosecution. The specific changes to the amended claims are shown above with the insertions being underlined. Therefore, Claims 22-26, 35-36 and 38-41 remain present for examination.

Applicants respond below to the specific rejections raised by the Examiner in the Office Action of August 21, 2003.

Discussion of Rejections under 35 U.S.C. § 112, First Paragraph

Enablement

Claims 35 and 37 remain rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claim 37 has been cancelled and the rejection of Claim 37 is not discussed herein. According to the Office Action, the specification is enabling for claims limited in scope to a nucleic acid having the sequence of SEQ ID NO:1, and a nucleic acid encoding a polypeptide having the sequence of SEQ ID NO:2. However, according to the Office Action, the specification does not reasonably provide enablement for isolated nucleic acid hybridization variants. According to the Office Action, the invention is not commensurate in scope with Claim 35 because the claim merely recites "hybridizes to" without specifying the hybridization conditions.

Claim 35 has been amended to recite isolated nucleic acids that hybridize under stringent conditions. Exemplary stringent conditions are set forth in the specification, for example, at pages 79-80. Therefore, amended Claim 35 is enabled because one of ordinary skill in the art can easily make and use the claimed hybridization variants without undue experimentation, given the teaching of the specification.

Thus, enablement is commensurate in scope with the amended claims. For these reasons, reconsideration and withdrawal of the enablement rejection in view of the amendments to the claims is respectfully requested.

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Discussion of Rejections under 35 U.S.C. § 102(e)

Claims 22-29 and 33-41 were rejected under 35 U.S.C. § 102(e) as being anticipated by Piddington et al., U.S. Patent No. 6,521,233 (referred to hereafter as “Piddington”).

In addition, Piddington does not anticipate Claims 22-26, 35-36 and 38-41 because Piddington fails to enable one of skill in the art to make and use the claimed invention.

A claim can only be anticipated by a reference if the publication describes the claimed invention with sufficient enabling detail to place the public in possession of the invention. *See In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996); *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051 (Fed. Cir. 2003) (“To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.” “Enablement requires that ‘the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation.’”); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003) (“A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.”); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75, F.3d 1558, 1566 (Fed. Cir. 1996) (“To anticipate the reference must also enable one of skill in the art to make and use the claimed invention.”).

Recently, the Federal Circuit Court of Appeals reversed and remanded a district court summary judgement finding the claims invalid under 35 U.S.C. § 102 because the district court failed to consider whether the cited prior art reference was enabling. *See Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 346 F.3d 1051 (Fed. Cir. 2003) (decided October 2003). The district court had determined that the claims were inherently disclosed by the prior art reference, and therefore, were invalid under § 102. *See id.* However, the Federal Circuit reversed that finding of invalidity under § 102 stating that the issue was “more properly characterized as enablement arguments rather than inherency arguments.” *Id.* Thus, the Federal Circuit stated that “[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.” *Id.*

Here, the Office Action stated Piddington anticipates because it inherently discloses the functional property of the claims. However, for the following reasons, Applicants respectfully assert that Piddington does not anticipate because it fails to enable the claims.

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The instant application claims priority from PCT Application No. PCT/US00/05601, filed on March 12, 2000. Piddington was filed on April 19, 2000, and claims priority from U.S. Provisional Application No. 60/130,199 (referred to hereafter as "the Piddington provisional application"), filed on April 20, 1999. Thus, for Piddington to anticipate, the Piddington provisional application must enable the claims.

Respectfully, Applicants assert that the Piddington provisional application fails to teach one of ordinary skill in the art how to make and use invention of Claims 22-26, 35-36 and 38-41 without undue experimentation, and therefore does not anticipate those claims. Claims 22-26, 35-36 and 38-41 as set forth above recite isolated nucleic acid variants, hybridization variants, and vectors and host cells comprising the variants. Claims 22-26 recite isolated nucleic acid variants that encode polypeptides which have the ability to induce chondrocyte redifferentiation. Also, Claims 35-36 recite nucleic acid hybridization variants that hybridize to nucleic acids that encode polypeptides which have the ability to induce chondrocyte redifferentiation.

The Piddington provisional application does not recognize the ability of any polypeptides to induce chondrocyte redifferentiation, nor does it disclose assays for determining chondrocyte redifferentiation. Therefore, the Piddington provisional application does not and cannot teach how to make and use the claimed isolated polypeptides because Piddington discloses nothing about chondrocyte redifferentiation or assaying for chondrocyte redifferentiation. It follows that the Piddington provisional application does not anticipate the claimed subject matter.

Thus, Piddington does not anticipate Claims 22-26, 35-36 and 38-41, because the Piddington provisional application does not provide sufficient detail to teach one of ordinary skill in the art to make and use the claimed isolated nucleic acid variants encoding polypeptides with the disclosed function.

Applicants, therefore, request that the Examiner reconsider and withdraw the rejections based on 35 U.S.C. § 102.

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CONCLUSION

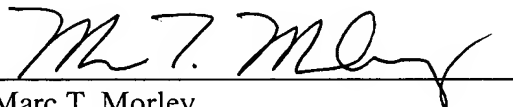
Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 11/20/03

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